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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/556,440	04/24/2000	Ruth A. Gjerset	INRP:032-2	7465

7590 07/14/2003

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EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/556,440

Applicant(s)

GJERSET, RUTH A.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-9 and 18-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-9, and 18-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Arguments

The response filed 5-23-03 (Paper No. 15) to the Office Action mailed 11-18-02 (Paper No. 13) is acknowledged and has been entered.

Claims 1, and 6-26 are pending.

Claims 10-17 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 1, 6-9, and 18-26 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 1, 6-9, and 18-26 remain rejected under 35 U.S.C. 102(e) as being anticipated by Roth *et al.* (US Patent No. 6,069,134, April 25, 1994) as evidenced by Jones *et al.* (Mutation Research, DNA Repair, 1991, Vol. 255, pages 155-162) for the reasons of record in Paper No. 13, pages 3-5.

Applicants argue (Paper No. 15, page 5) that the Roth patent is directed to methods of killing tumor cells by delivering p53 to the tumor cells and contacting the tumor cells with DNA damaging drugs (such as camptothecin) which is in contrast to claims directed to an inhibitory agent that inhibits DNA repair. Applicants argue that nowhere does the Roth patent disclose,

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claim, or suggest treating tumor cells by inhibiting DNA repair. Applicants concede (Paper No. 15, page 7), that while the Roth patent discloses DNA damaging drugs used in conjunction with p53 to induce apoptosis, the reference fails to disclose the method of the present invention, i.e. inhibition of DNA repair as a strategy to overcome tumor resistance to DNA damaging therapy.

These arguments have been considered but are not found persuasive. Applicant is reminded that the claims *define* the subject matter of the invention, and the specification cannot be relied upon to read limitations into the claims. Thus, while the specification may include inventions directed to the “inhibition of DNA repair as a strategy to overcome tumor resistance to DNA damaging therapy”, the claims are broadly drawn to a method for the induction of p53-mediated apoptosis in a cell comprising the steps of (a) introducing into said cell an expression construct comprising a nucleic acid segment encoding p53 and a promoter operably linked to said nucleic acid segment, and (b) contacting said cell with at least one inhibitory agent that inhibits DNA repair (Claim 1).

Applicants further argue against the validity of the data disclosed by Jones *et al.*, which experimentally concluded that camptothecin is an inhibitor of topoisomerase I. Instead, Applicants argue (Paper No. 15, page 7) that data more recent than that reported by Jones *et al.* suggest that camptothecin acts by “poisoning” topoisomerase I after the topoisomerase catalyzes the first strand break and before religation of the strand. These arguments have been considered but are not found persuasive. As a first matter, applicants have not demonstrated that the “poisoning” of an enzyme like topoisomerase I is not inclusive of said enzyme’s ability to function. Secondly, the arguments of counsel cannot take the place of evidence in the record. In

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this regard, applicant's attempts to discredit the teachings of Jones *et al.*, in the absence of any supporting literature or declarations, is not found persuasive.

Lastly, the specification fails to define the limitations of what is included or excluded as inhibitory agents that inhibit DNA repair. For example, the specification teaches (page 4, line 21), that "though *any* inhibitory agent of DNA repair may be used, the method advantageously employs [sic] inhibitory agents that inhibits the function of a protein selected from the group consisting of c-jun, c-fos, poly-ADP ribose polymerase, DNA polymerase β , topoisomerase I, *etc.*". The specification further teaches (page 4, line 27), that in one embodiment, "the inhibitory agent is a non-functional version of an agent involved with DNA repair." The specification further teaches (page 5, line 8) that the method may also comprise the step of providing a DNA-damaging agent. Thus, the claims contemplate and suggest the inclusion of *any* agent- as long as said agent inhibits DNA repair including inhibiting DNA repair at any time. This includes camptothecin- because whether it directly inhibits the enzyme topoisomerase I or causes DNA damage, the end result is that such an agent impairs the ability of the cell to repair its DNA. Thus, applicants arguments that the DNA repair inhibitors contemplated by the present invention act only at a specific step, ("after DNA damage has occurred and the cancer cell begins to mobilize the enzyme responsible for repairing the DNA damage it has sustained") are not persuasive for the reasons set forth above and because narrow limitations contained in the specification cannot be inferred in the claims. While the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into claims. On the contrary, claims must be interpreted as broadly as their terms reasonably allow. See *Ex parte Oetiker*, 23 USPQ2d 1641 (BPAI, 1992).

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Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the


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organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol Ph.D.
Examiner
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GBN
July 11, 2003


ANTHONY C. CAPIUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600